

# Can monitoring exhaled nitric oxide levels in outpatients improve the management of children with asthma?

<b>Submission date</b> 11/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/07/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/02/2015	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

Can monitoring exhaled nitric oxide levels in outpatients improve the management of children with asthma?

### Acronym

Exhaled nitric oxide study

### Study objectives

The aim of this study is to explore whether monitoring exhaled Nitric Oxide (eNO) levels in outpatients improves the management of children with asthma using a pragmatic experimental design.

The specific objectives are:

1. To determine whether using eNO levels in outpatients to direct therapy allows less inhaled corticosteroid to be used over a year of follow when compared to a control group
2. To determine whether using eNO levels in outpatients to direct therapy reduces the number of exacerbations that require treatment with systemic corticosteroid over a year of follow when compared to a control group

As per 09/02/2012, the anticipated end date has been updated from 31/08/2008 to 31/08/2009 and the target number of participants amended from 150 to 93.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Southampton and Southwest Hampshire Local Research Ethics Committee, 18/05/2006, ref: 06/Q1702/9

### Study design

Multicentre pragmatic prospective randomised double-blind study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Asthma

## **Interventions**

Current interventions as of 09/02/2012:

93 subjects aged 6 to 17 years with moderate or severe asthma will be recruited. Their asthma will be stabilised and they will be randomised to the exhaled nitric oxide (eNO) or control group.

All will be assessed every two months for a year. The control group will be managed according to the British Thoracic Society guidelines. In the eNO group, the inhaled corticosteroid doses will be increased in response to elevated eNO levels and reduced if levels are low. Subjects and medical staff involved in managing any exacerbations will be blind to group allocation.

An intention to treat analysis will be undertaken with a comparison of the change in inhaled corticosteroid dose and the number of exacerbations over the one-year follow up period between the two groups. It is expected that the eNO group will use less inhaled corticosteroids and experience less exacerbations.

Previous interventions:

150 subjects aged 6 to 17 years with moderate or severe asthma will be recruited. Their asthma will be stabilised and they will be randomised to the exhaled nitric oxide (eNO) or control group.

All will be assessed every two months for a year. The control group will be managed according to the British Thoracic Society guidelines. In the eNO group, the inhaled corticosteroid doses will be increased in response to elevated eNO levels and reduced if levels are low. Subjects and medical staff involved in managing any exacerbations will be blind to group allocation.

An intention to treat analysis will be undertaken with a comparison of the change in inhaled corticosteroid dose and the number of exacerbations over the one-year follow up period between the two groups. It is expected that the eNO group will use less inhaled corticosteroids and experience less exacerbations.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

An intention to treat analysis will be undertaken with a comparison of the change in inhaled steroid dose and the number of exacerbations over the one-year follow up period between the eNO and control groups.

## **Secondary outcome measures**

1. A per protocol analysis will be undertaken, the dataset for this analysis will be restricted to the subjects whose therapy was directed as per the protocol
2. Subgroup analysis restricted to subjects taking inhaled corticosteroid through a metered dose inhaler with a spacer as it is expected that these will form a more homogeneous analysis group

3. Subgroup analysis focusing firstly on subjects with moderate (400 - 800 mcg/day beclomethasone equivalent) and secondly subjects with severe (greater than 800 mcg/day beclomethasone equivalent) asthma to determine whether results are similar in both groups
4. Subgroup analysis focusing on firstly on atopic asthmatics and secondly non-atopic ones
5. Analyses restricted firstly to only viral associated exacerbations and secondly to exacerbations that are not associated with a viral infection
6. Comparison of the average inhaled steroid use in each group over the last six months of follow up

**Overall study start date**

12/12/2006

**Completion date**

31/08/2009

## Eligibility

**Key inclusion criteria**

1. Aged 6 - 17 years
2. Clinical diagnosis of asthma
3. Treatment with at least 400 mcg daily of beclomethasone/budesonide or 200 mcg daily of fluticasone

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

93

**Key exclusion criteria**

1. Inability to perform lung function or eNO measurement
2. Cigarette smoking
3. Poor compliance with medication
4. Previous life-threatening exacerbations
5. Need for maintenance oral prednisolone

**Date of first enrolment**

12/12/2006

**Date of final enrolment**

31/08/2009

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Southampton University Hospital NHS Trust

Southampton

United Kingdom

SO16 6YD

## **Sponsor information**

**Organisation**

University of Southampton (UK)

**Sponsor details**

Research Governance

Legal Services

Building 37

Highfield Road

Southampton

England

United Kingdom

SO17 1BJ

**Sponsor type**

University/education

**Website**

<http://www.soton.ac.uk/>

**ROR**

<https://ror.org/01ryk1543>

## **Funder(s)**

**Funder type**

Charity

### Funder Name

Sport Aiding Medical Research for Kids (SPARKS) (UK)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2013		Yes	No